

U.S. Serial No.: 10/629,978
Filed: July 30, 2003
Group Art Unit: 3739
Examiner: Peter J. Vrettakos
Atty. Docket No.: 22956-324

REMARKS

The pending Office Action addresses and rejects claims 38-40, 42-57, and 68-73.

Claim Rejections

(1) Independent Claims 38, 47, 49, 52, 57, and 72

Claims 38-40, 42-45, 52, 54, 57, and 72 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,702,397 of Goble et al. ("Goble"), and claims 47, 49, 51, 53, and 56 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Goble. With regard to independent claims 38, 52, 57, and 72, the Examiner argues that Goble discloses a device for anchoring a filament to tissue or bone having an anchor member and an insertion element that are adapted to hold a suture therebetween by interference or compression. The Examiner argues that the mechanical interlock used in the Goble device causes friction to hold the suture therebetween. The Examiner states that "[t]he ridges 'force fit' secures the suture." With regard to independent claims 47 and 49, the Examiner argues that it would have been obvious to one of ordinary skill in the art to modify Goble in light of routine experimentation to provide a suture anchor having a filament that moves as claimed. Applicants respectfully disagree.

Independent claims 38, 47, 49, 52, 57, 68, and 72 each require a suture anchor that is adapted to hold a suture by an *interference* or *compression* fit. An interference or compression fit is a specific type of fit that is created when one or both contacting surfaces of the suture anchor yield to create an amount of normal compression forces between the surfaces. The compression forces provide a frictional force to retain the suture between the contacting surfaces in secure engagement under axial or rotational loading. As a result, the use interference or compression fit in a suture anchor can allow a suture retained between the two components to move or slide before it breaks. This is particularly advantageous as breakage of the suture will result in failure of the anchor.

Goble does not teach or even suggest a suture anchor that uses an interference or compression fit to retain a suture. Rather, Goble uses a *mechanical interlock* to retain a suture, as shown in Figures 13, 16, and 17. A mechanical interlock is different than an interference or compression fit, as it is created when two parts are held together by corresponding surface features

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which positively engage one another to hold the components together. Aside from being entirely an different type of engagement than the interference or compression fit required by the pending claims, the device disclosed by Goble also performs differently. The use of a mechanical interlock in the suture anchor disclosed by Goble will prevent movement of the suture altogether due to the corresponding ridges used to lock the two components together. As a result, a suture trapped between Goble's mechanically interlocked components will likely break before it moves. In fact, the use of a mechanical interlock may cause the suture to break during normal use as the mechanical interlock between the ridges could potentially damage the suture.

The mechanical interlock disclosed by Goble is therefore distinct from the claimed interference or compression fit, and any person having ordinary skill in the art appreciates and understands these differences, as evidenced by the attached §1.132 Declaration of Mehmet Sengun. Accordingly, claims 38, 47, 49, 52, 57, 68, and 72 distinguish over Goble and represent allowable subject matter. Dependent claims 39-40, 42-48, 50-51, 53-56, and 69-71 are allowable at least because they depend from an allowable base claim.

(2) Independent Claims 68 and 73

The Examiner also rejects claims 50, 55, 68-71, and 73, all of which require a frangible portion, pursuant to 35 U.S.C. § 103(a) as being obvious over Goble in view of Reissue Patent No. 36,289 of Le et al. ("Le"). Applicants respectfully disagree.

As shown in Figures 16 and 17, Goble discloses a tool (70) that is used to rotate and drive a set screw (60) into a plug (50) that is disposed within the anchor (40). The tool (70) includes several short posts (74) formed on the distal end thereof and adapted to be disposed within corresponding holes 64 formed in the set screw (60). The Examiner argues that it would have been obvious in view of Le to modify the tool (70) to be frangibly coupled to the plug (60) to facilitate removal of the tool. This is incorrect for several reasons.

First, it would not have been obvious to modify the anchor of Goble to include a frangible connection as taught by Le because such a modification would interfere with the intended function of the Goble anchor. The anchor disclosed in Figures 16 and 17 is specifically designed to allow the suture to be released. Thus, when the anchor is first implanted, the tool is used to thread the set

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screw (60) into the plug (50) to lock the sutures in place. When release or adjustment of the suture is later desired, for example to adjust the tension of the ligament, the tool can again be inserted through the anchor (40) to rotate the set screw (60) in an opposite direction to release the suture from the anchor. (See Col. 4, line 60 to Col. 5, line 7, and Col. 10 lines 51-59.) The use of a frangible connection to mate the tool to the set screw, as suggested by the Examiner, would prevent the tool from being used as required by Goble to adjust the tension or release the suture. Once the tool is frangibly removed from the set screw the tool cannot be used again to rotate the set screw. Accordingly, the use of a frangible connection is specifically contrary to the teachings of Goble and would render the device useless for its intended purpose.

Furthermore, there is no motivation to modify the anchor of Goble to include a frangible connection as taught by Le. Le utilizes a frangible connection to allow the tool to be used to engage and guide the wedge member onto the anchor. This is not necessary with the Goble device because the set screw (60) is pre-disposed within the anchor. The use of any type of frangible connection with the Goble device would therefore be disadvantageous. A frangibly attached rod would render the device more difficult to operate, as the rod would have to be separated from the set screw. Goble already provides a simple and effective method for inserting the set screw into the plug of the bone anchor.

In a telephone call with the Examiner on May 26, 2005, the Examiner also argued that Goble inherently discloses a frangible connection between the tool and the set screw. For the same reasons stated above, Applicants respectfully disagree. The Goble anchor is specifically designed to allow for release or adjustment of the suture, as may be necessary over time. The tool therefore cannot be inherently frangible as this is specifically contrary to the teachings of Goble. The tool is further not inherently frangible as it does not include a reduced diameter region that would allow the tool to break apart from the set screw. The entire shaft of the tool has a substantially constant, rather large diameter, and the distal end of the tool has an increased diameter. No portion of the tool includes a reduced diameter region that would allow for breakage to occur. Even if breakage could occur, this would be undesirable as the distal end of the tool would be left floating in the patient's body since it is not attached to the set screw.

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The Examiner's reliance on an allegedly inherent disclosure by Goble is also misplaced. "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* at 1269, 20 U.S.P.Q.2D (BNA) at 1749 (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981)). The frangible connection that is missing from the Goble reference is clearly not necessarily present, and it certainly would not be so recognized by persons of ordinary skill. In fact, Goble cannot be relied on to establish inherency because Goble specifically requires that driver tool be separate from the set screw to allow for later adjustment. The Examiner has not provided any basis in fact or technical reasoning to support a determination that a frangible connection on the tool necessarily flows from the teachings of Goble.

Accordingly, claims 50, 55, 68-71, and 73 distinguish over Goble and Le and therefore represent allowable subject matter.


Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,



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